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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,547

01/26/2004

Seung-Hak Choi

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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

09/03/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/765,547	Applicant(s) CHOI ET AL.	
	Examiner SHUBO (Joe) ZHOU	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/09 has been entered.

Status of the Claims

Claims 1-14 are currently pending and under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejection is reiterated from the previous Office action mailed 11/18/08.

This rejection is reiterated from the previous Office action, which is consistent with the Office's recent "Interim Examination Instructions for Evaluating Subject Matter Eligibility

Art Unit: 1631

Under 35 USC 101,” effective August 24, 2009, which is available at the Office's website at http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf.

As set forth in the Interim Examination Instructions (pages 4-5), a process claim, to be statutory under 35 USC 101, must pass the machine-or-transformation test (M-or-T test), that is, a claimed process must:

- (1) be tied to a particular machine or apparatus; or
- (2) particularly transform a particular article to a different state or thing.

In the instant case, while the amended claims recite in the preamble that the method is performed in a system which comprises a processor, and recites storing the result in a system and outputting to a user in the last two steps, the claimed process is not tied to a particular machine or a particular apparatus. The Interim Instructions state point out that the particular machine tie or particular transformation must meet two corollaries to pass the test for subject matter eligibility. First, the use of the particular machine or transformation must impose meaningful limit on the claims's scope. So, a machine time in only a field of use limitation would not be sufficient. Second, the use of the particular machine or the transformation of the particular article must involve more than insignificant extra-solution activity. If the machine or transformation is only present in a field of use limitation or in a step that is only insignificant extra-solution activity, the claim fails the M-or-T test, despite the presence of a machine or a transformation in the claim. See page 5 of the Instruction. In the instant case, the preamble and the steps of storing and outputting would fall into this category of insignificant extra-solution activities. The court has also pointed out that the involvement of the particular machine/apparatus or transformation in a

Art Unit: 1631

claimed process must not merely be an insignificant extra-solution activity. See *Flook*, 437 U.S. at 590.

Additionally, while the steps refer to biochip, which is interpreted as a machine or apparatus, it is actually the “results of the biochip” that are analyzed in the claims without requiring that the biochip itself be used in the claims.

Moreover, there is no physical transformation achieved by the claimed process.

This rejection could be overcome by amending the claims to produce a physical transformation or tie to a particular machine or apparatus in steps that are not insignificant extra-solution activity. Applicant, however, is cautioned against introducing new matter in the amendment.

Claim Rejections-35 USC § 112

The rejection of claims 1-14 under 35 U.S.C. 112 , second paragraph, for reasons set forth in the previous Office action is withdrawn in view of applicant’s amendment filed 7/29/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1631

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne et al. (IDS document: Artificial Intelligence System for Genetic Analysis, WO 01/16860 A2, March 8, 2001).

The claims are amended to be drawn to a method or a server-client network system for genotyping analysis on a target sample. The network comprises a server including an analysis algorithm database for the genotyping analysis and a client system communicatively coupled to the server, which receives the results of a biochip test on the target sample, identifies a biochip on the target sample, selects and downloads an analysis algorithm for the chip, performs the genotyping analysis and stores and output the results to a user, wherein the selected algorithm is

Art Unit: 1631

established using statistical data for results of performing testing on a number of patient and reference samples using the biochip.

Absent an explicit definition in the specification, the term "analysis algorithm" is interpreted as any algorithms for any analysis.

With regard to at least independent claims 1 and 12, Osborne et al. disclose a network system and a method for genetic analysis. The network system comprises a server that includes multiple databases required for the genetic analysis, which are provided to client that receives the results of a microarray analysis and performs the genetic analysis. See at least Fig. 1 and pages 4-6. The genetic analyses include analysis of genomic mutations (see page 12, lines 30-31), which is interpreted as a type of genotyping. Osborne et al. disclose that the system comprises central data processing facilities and user facilities and that "each user facility may include an optical scanning system to collect hybridization signals from a nucleic acid array, an image processing system to convert the optical data into a set of hybridization parameters, a connection to a data network, and a user interface to display, manipulate, search, and analyzed hybridization information." See page 5. The system comprises various types of users at different tiers including remote users/local users, web users/internet users, diagnostic users including diagnostic master users, and browser users (see pages 10-12), any and all of which is interpreted as being part of the client system as recited in the instant claims. Since the user facilities (interpreted as client) and the central data processing facilities (interpreted as server) comprising the databases are linked by encrypted network connections (see page 5), it is interpreted that the databases in the server are provided to the client and that the client system is communicatively coupled to the server.

Furthermore, Osborne et al. state on page 12:

Art Unit: 1631

There are two categories of diagnostic users, such as "diagnostic master users" and "diagnostic users". Accounts for diagnostic master users are authorized and correspond to the user sites where the systems are deployed. These diagnostic master users are allowed to authorize accounts for diagnostic users. For clinical applications, diagnostic users correspond to the individuals that have been tested. For research and development applications, diagnostic master users can designate either individual chip test results or groups of chips as a single diagnostic user, wherein this option lies with the diagnostic master users in order to meet their testing and analysis needs. Diagnosis processing is a key part of the artificial intelligence system. The diagnosis processing for clinical applications may be different from that of research and development applications. Diagnosis processing for clinical applications implements a rules-based analysis application which utilizes a database set of rules and results. Diagnosis processing thereby determines which conditions apply to the various combinations of gene expression levels and personal medical history.

The accounts authorized to diagnostic users are also interpreted as part of the client system as the accounts correspond to the user sites. Additionally, this statement clearly indicates that for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives (i.e. downloads) the systems because they "are deployed," and the system includes databases of rules, etc., which are interpreted as analysis algorithms.

With regard to the limitation of identifying the biochip for the target sample, while Osborne et al. do not explicitly disclose identifying the biochip for the target sample, the databases in the server disclosed by Osborne et al. include database for chip ID and pattern/layout, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for analysis of the biochip data and the biochip has identifier, it is interpreted the chip ID is to be used for identifying the chip (biochip

Osborne et al. do not explicitly disclose that the analysis algorithm is established using statistical data for results of performing testing on a number of patient and reference samples using the biochip.

However, it would have been obvious to one having ordinary skill in the art that in order for Osborne's rules to be used by users for the analysis of diagnostics, or any rules for anybody to use for diagnostic analysis of a disease, such rules would have been established on the basis of previous test or diagnostic results on patients and compared with normal individuals using statistical data and tests.

With regard to claims 2 and 13, the databases in the server disclosed by Osborne et al. include database for chip ID and pattern/layout, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for analysis of the biochip data and the biochip has identifier, it is interpreted as the algorithm is relevant to the biochip identifier in view of the indefiniteness of the limitation set forth above.

With regard to claims 3-4, the server of the system by Osborne et al. comprises database that is built up from statistical data for the results of test on a number of patients and references samples using microarrays. Osborne et al. disclose that the database server stores hybridization profiles, patient profiles, reference information, clinical information associated with hybridization profiles, and statistical summaries. See page 5. Osborne et al. further disclose that "hybridization profiles collected by remote and/or local facilities include clinical observations or other information associated with each profile, and the profile with associated observations is added to the central database." See page 6. Osborne et al. also state that "the databases of the instant invention continually mature and develop into more and more complex systems as

information from public and private sources continues to be added to the existing database.” See pages 13 and 15. Thus, the databases are being built up while the users use the system.

With regard to claim 5, in the system disclosed by Osborne et al., the users/clients comprise optical scanning system and identifier recognizer. See at least Fig. 1 and pages 11 and 16.

With regard to claims 6-8 and 14, which include limitations that the client comprises an engine for performing a series of logical functions, in the system disclosed by Osborne et al., the client comprises an engine or means for performing a function of detecting the identifier of the biochip (see Fig. 1 and the “application ID on at least page 16, array ID and array location ID on at least pages 26-27, and sample ID, patient ID, etc. on pages 28-29). Client can select and download data/database based on application ID, etc., and perform genotyping analysis. See the diagnostic architecture listed on pages 16-18. Furthermore, with regard to claim 8, the method of Osborne et al. allows client to perform the genetic analysis including reading results via scanning system, (see pages 16-18), linking results with spot position information of the chip, etc. (see pages 13-14, where the database queries include chip ID genetic pattern, pattern match, result output, etc. and page 15). Users can perform functions such as correlating the hybridization signals of one or more probes and creating test hypothesis relating to a particular pathological or physiological condition, using the server databases to search, correlate, manipulate and display existing data, etc. See page 15.

With regard to claims 9-11, which are drawn to computer readable medium comprising computer executable instructions for executing the method steps and functions performed by the system above, given that the system for performing the functions and method steps as set forth above is a web-based computer systems including server and client, it would be readily

Art Unit: 1631

recognized by one skilled in the art that the system inherently comprises computer readable medium containing computer executable instructions for performing the functions.

Applicant's arguments filed 7/29/09 have been fully considered but they are not found persuasive.

After summarizing the Office action, applicant argues that the applicant "finds no suggestion or teaching in Osborne of the web, database, application or operations server as including 'databaes of rules' so as to teach the 'analysis algorithms' of the claimed invention," etc. See page 13 of 16. This is not found persuasive. As set forth in the previous Office action in responding to applicant's similar argument, Osborne et al. clearly disclose that their invention provides "a complete system" and databank for array analysis and clinical analysis. The system includes neural network algorithms among other things. See page 4. Osborne et al. also disclose that "[i]n another manner of practicing the invention, users perform statistical tests on cataloged hybridization profiles stored in the central data processing facility ... users create and test hypothesis relating hybridization information to particular pathological or physiological states. Clearly, this would be done in a system like the web or internet. A variety of statistical analyses are provided to suggest and evaluate hypothesis" (see page 6, emphasis added by the Office). Since the system of Osborne et al. is an artificial intelligent system with neural network algorithms, etc., it would have been obvious to one having ordinary skill in the art that these "variety of statistical analyses" that are provided "to suggest and evaluate hypothesis" are algorithms for the analysis, which are thus analysis algorithms, and if they "are provided," they must be provided to a user of the system of Osborne et al including the rules in the database.

Art Unit: 1631

Applicant then argues that even if the user receives the system including web, database, etc, there is still no teaching or suggestion by Osborne as to what or who starts or triggers a transfer of the system so that the user receives the system. Applicant then concludes that Osborne thus does not teach or suggest the client system performing downloading the selected analysis algorithm. See page 14 of 16 of the response. This is also unpersuasive.

First, applicant is arguing limitations that is not in the claims, i.e. what or who triggers the transfer of the system. Secondly, as set forth above in the paragraph cited from Osborne (page 12) , Osborne explicitly disclose that for one application, accounts for diagnostic master users are authorized and correspond to the user sites where the systems are deployed; that for research and development applications, diagnostic master users can designate either individual chip test results or groups of chips as a single diagnostic user, wherein this option lies with the diagnostic master users in order to meet their testing and analysis needs, and that diagnosis processing is a key part of the artificial intelligence system and the diagnostic processing for clinical applications implements a rules based analysis application which utilizes a database set of rules and results. It would have been obvious to one having ordinary skill in the art that if the systems are deployed, they must have been provided to the users. The result is the system is deployed and transferred, regardless of what and who triggers the transfer, which is not a claim limitation.

It should be pointed out again that Osborne et al. disclose many different inventions and there are many different applications for the systems therein, as evidenced by such phrases as “one aspect of the present invention,” “In another manner of practicing the invention” (page 5) and “in some manners of practicing the invention” (page 6).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER